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Claims

1. A method for sequence-based diagnosis of a human neoplastic tissue, blood or other body fluid sample, by analysing from genomic DNA or cDNA derived from said neoplasia the DNA sequence of a gene encoding the cancer-related p 53 protein for the presence of mutations therein, characterized by a) determining from the presence, nature and location of any such mutation or mutations the influence thereof on the biological function of the corresponding protein and thereby on the properties of the neoplasia, b) classifying the neoplasia into different subgroups depending on (i) the presence or not of a mutation, and (ii) whether the patient is node positive or not, and on the basis thereof prognosticating the development of the neoplasia and provide a guidance for adequate treatment of the patient.

2. The method of claim 1, characterized in that said properties of the neoplasia includes biological aggressiveness and/or metastatic potential.

3. The method of claims 1 or 2, characterized by analyzing a part or parts of the gene which encode at least one biologically functional domain of the cancer-related protein.

4. The method of claim 3, characterized in that said biologically functional domain includes a DNA binding domain and/or transactivation site.

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5. The method of ~~claim 3 or 4~~ claim 3, characterized in that evolutionary conserved regions of the gene are analyzed.

6. The method of claim 1, characterized in that the neoplasia is a breast, lung, prostate, gastric, colorectal, melanoma or leukemia neoplasia.

7. The method of claim 6, characterized in that said sample originates from a breast neoplasia.

8. The method of claim 7, characterized in that the detection of the presence of a p53 mutation in a node negative patient tumour sample is indicative of the need of adjuvant therapy following surgical removal of the tumour.

9. The method of claim 8, characterized in that the adjuvant therapy is radiation or chemotherapy/hormone therapy.

10. The method of any one of ~~claims 1 to 9~~ claim 1, characterized in that it comprises one or more of the following steps: preparation of genomic DNA or cDNA, amplification of at least part of the cancer-related gene, processing of the cancer-related gene including sequencing reactions, and detection of the products from the sequencing reactions in an automated nucleic acid sequencer, computer software optionally being used to (i) track samples and control process steps and/or (ii) to aid in and/or interpret sequence data obtained.

11. A method of detecting mutations in a gene, characterized by comprising the steps of preparing genomic DNA or cDNA, amplifying at least part of the gene, processing the amplified DNA to produce sequencing reaction products, preferably by solid phase based techniques, detecting the sequencing reaction products in an automated nucleic acid sequencer to determine a DNA sequence or sequences of the p53 gene, and comparing the sequence or sequences with the corresponding wild type p53 gene sequence or sequences, computer software being used to (i) track samples and control process steps and/or (ii) to at least aid in interpreting sequence data obtained.

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12. The method according to claim 11, characterized in that mutations are detected in a gene encoding the p53 protein.